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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,255	08/20/2002	David Wallach	WALLACH=28	2930

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EXAMINER	
SCHULTZ, JAMES	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,255	WALLACH ET AL.	
	Examiner	Art Unit	
	J. D. Schultz, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,10-13,30,32,33,35 and 36* is/are pending in the application.

4a) Of the above claim(s) *32 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 5, 10-13, 30, 33, and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 14 August 2006 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 4 January 2006 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicants have argued that only generic linking claims remain, which do not read on the prior art that was used to demonstrate that applicants' special technical feature did not constitute a contribution over the prior art, and that the restriction requirement among the three IREN sequences should be withdrawn as a result.

This is not convincing for two reasons. First, there is no generic claim that embraces all three IREN sequences. The claim at issue is in fact a Markush claim, since it lists the three specific sequences in the alternative. In a linking claim, generic language would be used to embrace all three sequences without naming each specifically. As a 35 USC 371 filing, Markush style claims may be restricted if the claimed subject matter does not share unity of invention. This leads to the second issue. The claim lacks unity of invention, since while each sequence is related, they do not share a common function that emanates from a common core structure. As a

matter of form, it is noted that the last action made the restriction requirement final. Accordingly the proper course at this stage of prosecution is a petition. See 37 CFR 1.144.

This application contains claims 32, and 34, and subject matter of claims 1, 2, 5, 10-13, 30 and 32, that contain subject matter NOT drawn to the elected nucleotide sequence encoding IREN (i.e. SEQ ID NO: 4) drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Finally, claims 33 and 36 were not previously treated on the merits due to their improper multiple dependence. However, now that they have been amended and can be treated on the merits, it is apparent that they contain inventions that do not share unity of invention with the elected DNA sequence encoding the protein IREN for the same reasons as set forth in the action mailed 9 August 2006. Accordingly, the subject matter drawn to a protein encoded by SEQ ID NO: 4, a molecule capable of disrupting the interaction of the protein encoded by SEQ ID NO: 4 with TRAF2, and any molecule to which said protein encided by SEQ ID NO: 4 binds are all withdrawn as being drawn to a non-elected invention.

Notice of Non-Compliant Amendment

The claims are not considered to be in compliance with 37 CFR § 1.121.

§ 1.121(c) Manner of making amendments in applications.

(c) Claims . Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a

parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

Claims 32 and 34 are noted as currently amended, when in fact they have also been withdrawn, and should be noted as such. Applicant may note a claim in such a status as (withdrawn, currently amended).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is drawn to transformed eukaryotic or prokaryotic host cells containing a vector according to claim 10.

Claims 13 is rejected under 35 USC §101 because the claimed invention is directed to non-statutory subject matter. The term "cell" encompasses a human egg or human embryo. The scope of the claim, therefore, encompasses a human being, which is non-statutory subject matter. As such, the recitation of the limitation "isolated" would be remedial. See 1077 O.G. 24, April 21, 1987.

Claim Rejections - 35 USC § 112

Claim 36 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA molecule encoding SEQ ID NO:4, does not reasonably provide enablement for a pharmaceutical composition therefore, nor any such composition capable of

"preventing" any disease associated with SEQ ID NO: 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 36 is drawn to a pharmaceutical composition for the prevention or treatment of a any pathological condition associated with NF-KappaB induction, comprising an effective amount of a DNA molecule encoding SEQ ID NO: 4. The factors listed below have been considered in the analysis of enablement:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification as filed does not provide any examples that would enable a skilled artisan to use the disclosed compound of SEQ ID NO: 4, or its translated product, IREN, to receive any pharmaceutical benefit, or to prevent a representative sample of diseases from the genus of any disease. Additionally, a person skilled in the art would recognize that deriving pharmaceutical benefit from the use of SEQ ID NO: 4 in the absence of any exemplified teaching is highly problematic, since the prior art is silent as to such pharmaceutical uses, let alone the prevention of any disease using same. Thus, although the specification prophetically considers and discloses general methodologies of using SEQ ID NO: 4, such a disclosure would not be considered enabling for therapeutic treatment or prevention of any disease is highly unpredictable, since the prior art is apparently silent on the use of IREN as a pharmaceutical, as

is the instant specification in any capacity other than prophetically. This is particularly true in view of the lack of guidance in the specification and known unpredictability associated with the prevention of any disease using a pharmaceutical composed of DNA encoding IREN. Accordingly, one of skill in the art would have been unable to practice the invention without engaging in undue trial and error experimentation as presented in the specification over the scope claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 and 103 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> 102 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> 103 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5, 10-13, 30, 33, and 36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wallach et al. (of record).

The claims are drawn to the cDNA sequence of SEQ ID NO: 4, or degenerate variants thereof, and to vectors, host cells, and pharmaceutical compositions thereof.

Wallach et al. teaches SEQ ID NO: 1, which comprises the instant SEQ ID NO: 4, differing only at four nucleobases over the entire sequence, wherein said four differences are all marked in the prior art reference as wild-cards ("N"). When the reference teaches a small genus, as in the instant case, the claimed species is considered to be in the possession of the public as in

In re Schaumann, 572 F.2d 312, 197 USPQ 5 (CCPA 1978). Wallach et al. also teaches vectors, host cells and pharmaceutical compositions thereof.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. D. Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JDS

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER